A Randomized, Controlled Pilot Study of a Patient-Initiated Approach to Increasing Weight Communication in Primary Care

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Study Protocol and Statistical Analysis Plan

Research staff gave a brief presentation to all physicians about the study prior to study initiation. Physicians were told about the study generally and shown the pamphlets briefly. Research staff answered any questions. Physicians were instructed to continue their clinical care as usual.

Participants and Enrollment Process

Participants were recruited from the waiting room from a Drexel University Family Medicine office in Manayunk (Northwest Philadelphia). Once patients checked-in to their appointment, research staff approached all patients. If it was clear the patient was not available for conversation after check-in (e.g., patient speaking on the phone), the patient was not approached. When the waiting room volume was too high for the staff, every third patient was approached (of note, this only occurred once over the course of recruitment). Staff inquired regarding interest in participating in a brief research study while they waited for their appointment. Participants were invited to read a brief recruitment flyer or the consent form for additional information. Staff offered to meet privately with any patients who had questions. If the participant indicated verbal interest, he or she was provided with the consent form and a screening questionnaire. The screening questionnaire assessed 1) birthdate, 2) ability to read English, 3) pregnancy status, 4) if the patient's appointment was with a physician, 5) purpose of appointment, 6) height, 7)weight, and 8) figure shape he or she believed matched their body (Stunkard, Sørensen, & Schulsinger, 1983). The topics for the purpose of appointment were indicated from a list of most common appointment topics in primary care, including but not limited to weight, blood pressure, diabetes, immunization, mood, cholesterol, sickness/infection, and other. Eligible participants were 18 or older, able to read English, had an appointment with

physician (i.e., an appointment not only for bloodwork), and indicated a shape associated with overweight or obesity (Shape 5 and higher). Exclusion criteria were pregnant or not able to read/understand the form. Enrollment continued until 60 eligible participants were enrolled, randomized, and completed all study procedures. A total of 62 participants were enrolled and randomized, however, one participant left before completing measures and one participant was accidentally enrolled (she was pregnant), and was excluded from analyses, leaving 60 participants for analyses.

2.2 Procedure

After eligibility was confirmed by the screening questionnaire, eligible participants were randomized to either the intervention or control condition. A randomization scheme was generated by Sealed Envelope (Seed #: 142681324665211, Sealed Envelope Ltd., 2017). Randomization was stratified by whether the participant was planning to discuss weight with their physician or not. Randomization was blocked by groups of 2, 4, and 6 to ensure an equal number of participants in each condition. The participant and research staff were blinded to the assignment until after the participant was deemed eligible. After randomization, control participants were instructed to proceed to their appointment and then remain after their appointment for brief questionnaires. Participants in the intervention condition received the intervention pamphlet and instructions to read and answer the questions in the pamphlet prior to their appointment. They did not receive any clinician aid with the pamphlet, but instead were instructed to read and fill out the pamphlet while they waited for their appointment. Intervention participants were also instructed to see the research staff for the post-visit assessments after their appointment.

The experiential intervention pamphlet addressed barriers to patient-initiated weight discussions, including knowledge of weight status and the implications of weight, confidence in physicians' abilities to treat weight, stage of change for weight-related behaviors, and comfort in discussing weight. The pamphlet was organized into four modules. In the first module, "What affects my weight?" participants were asked to identify which factors they believe affect weight. Subsequently information was provided that many factors affect weight and informed that while weight is not their fault, they can make changes to positively affect their weight. On the second module, "How does my weight affect my health?" participants were asked to use a wheel (provided to them) to identify their BMI. Presented next were recommendations for different BMIs for the patient to improve their health and questions for the patient to ask his or her physician about how their weight affects their health. The third module, "Am I ready to make changes?" assessed stage of change and provided recommended questions for the participant to ask their physician based on their response. Also included in this section was a statement to address potential fear of weight bias: "It's okay if your weight, eating, or activity are difficult topics discuss. Your doctor is here to help you with your health." On the fourth module, "I want to learn more by speaking with my doctor," included a summary of the questions in the pamphlet. General resources for obesity were also included in the pamphlet.

After the scheduled appointment all participants completed the post-visit assessment. This assessment asked participants to report gender, race, and ethnicity. Participants were also asked to rate their health and complete a single-item health literacy question. Lastly, participants reported the topics discussed in the appointment from the same list of potential topics for their appointment from the screening measure. If a participant indicated that they discussed weight, they were directed to complete additional questions regarding their weight conversation.

Intervention participants were asked to answer additional pamphlet acceptability questionnaires. Intervention participants were given 10 dollars after responding to the acceptability questionnaires. The experiential pamphlet was either collected or photographed by research staff at the conclusion of assessment.

Staff and physicians were recruited for acceptability interviews after the conclusion of data collection. Physicians who staffed the clinic at times when the research staff were present, and thus may have interacted with a patient with the intervention, were invited to participate in the interviews by email. Physicians and staff were also informed of their anonymity, that their responses would not affect their position, and that they could elect to not answer any question.

Measures

Feasibility and Acceptability. The flow of participants was tracked to assess feasibility. This included tracking the number of participants approached, the number of interested participants, reasons given for declining participation, the number of eligible participants, and the amount of the pamphlet that is completed.

Acceptability was assessed with intervention participants after the conclusion of the appointment. Acceptability questions were adapted from the Treatment Acceptability Questionnaire and included assessment of how acceptable the participants found the experiential pamphlet, how ethical they thought the pamphlet to be, and if they think the pamphlet could have a negative impact (Hunsley, 1992). Scores can range from 6 to 42, with higher scores representing higher ratings of acceptability. Scores above 21 are considered to represent an acceptable treatment. Participants were asked if they would recommend the pamphlet to others and if they would use the pamphlet or questions included in the pamphlet again at a later time. Participants were provided with space to additionally comment on the intervention. Target

engagement was evaluated by asking participants to report one piece of information from the pamphlet.

At the conclusion of data collection, select physicians were queried to assess physician acceptability. Physicians were queried on how patients utilized the pamphlet (e.g., specific questions asked, or patients bringing out pamphlet to show physician). Physicians were asked about the course of appointments after patients utilized questions from the pamphlet and asked about the quality of weight-related discussions that ensued after patients initiated discussions. Physicians were specifically asked if they felt there was a time burden from the pamphlet or questions from the pamphlet, or if the usage of the pamphlet disrupted other aspects of the appointment. Physicians were also shown the pamphlet and asked for feedback on content and overall acceptability of a intervention with patients prior to the appointment. Physicians were also given a brief survey, including the Treatment Acceptability Questionnaire and other questions to assess acceptability (e.g., "if clinically indicated, would you like your patients to receive this pamphlet before their appointment?"). Benchmarks for physician acceptability were not set a priori due to the small sample size (n=6, 20% of physicians at the practice and 33.3% of physicians who worked while the research staff recruited participants). Interviews with physicians were recorded and then later transcribed for analyses.

Front office staff (n=4) were also interviewed to assess their acceptability of a waiting room intervention. This study sought their opinion because the front office staff would need to implement any future waiting room intervention and staff spend more time in the waiting room atmosphere than physicians. Research staff conducted brief interviews with the four staff members who oversee the waiting room (two medical assistants and two medical receptionists)

to assess acceptability of a waiting room intervention generally. Interviews were recorded and then transcribed for analysis.

Frequency of weight communication. If a patient indicated that they discussed weight in their appointment, he or she was asked to answer further questions to specify the content of the discussion. The patient must have indicated that at least one of the 5As occurred for the communication to be categorized as a weight-related discussion. Examples included: PCP asked readiness for change or motivation (ask); calculation of BMI, discussion of behavioral and/or biological factors of obesity, assessment of family history (assess); discussion of one or more of the risks of obesity, discussion of treatment options and how to lose weight (advise); decide on current weight-related goals (agree); physician provided referral to weight loss treatment (assist). Patients were also asked who initiated the discussion of weight-related topics and if weight had been discussed in prior appointments.

Covariates. General health and health literacy were assessed on the post-assessment measure as potential covariates. Participants were asked to rate their health on a single question ("How would you rate your general health?"). Variations of this single-item have been shown to be valid, reliable, and have been used widely in government and insurance surveys (Bowling, 2005). A one-question assessment of health literacy was included, "how confident are you filling out medical forms by yourself?" A brief measure of health literacy was necessary given the fast-paced primary care setting. Additionally, there are benefits to asking about experiences of health literacy rather than directly testing it to avoid discomfort or embarrassment (Al Sayah et al., 2013). Previous studies demonstrated the predictive validity of two single-item questions, "how confident are you filling out medical forms by yourself?" and, "how often do you have someone help you read hospital materials?" In a study that compared those two questions and

examined them with other, longer, and direct measures of health literacy, the question with the highest sensitivity was, "how confident are you filling out medical forms by yourself?" (Chew et al., 2008). Therefore, this single-item measure was chosen due to its brevity and support in the literature.

Data Analysis

SPSS version 25 was utilized for all statistical analysis. All data was examined prior to analyses to test assumptions and appropriate corrections made if necessary. Missing data was examined. Demographic characteristics were compared across conditions and covariates controlled for as needed. All *p* values represent two-sided hypothesis tests and the significance level was set at 0.05.

Statistical Analysis

Hypothesis 1. The hypothesis that the experiential pamphlet intervention is feasible was tested by calculating the percentage of participants in each category as defined in Table 1 and comparing those to pre-set benchmark values. Comparisons were made with nonparametric Mann-Whitney U tests. Acceptability was tested with participant and physician reported acceptability. Participant acceptability would be indicated by a score of >21 on the Treatment Acceptability Questionnaire (Hunsley, 1992). Physician and staff interviews on acceptability were audio-recorded, transcribed, coded, and analyzed to assess acceptability. An iterative process based on grounded theory of qualitative research was utilized throughout the analyses.

Hypothesis 2A: The hypothesis that intervention participants had a higher likelihood of engaging in patient-initiated weight discussion was tested with logistic regressions. The independent variable was the intervention condition (intervention or control). The dependent variable was categorical and categorized as a participant having a patient-initiated weight discussion with at least one aspect of the 5As vs. a participant not initiating the discussion.

Hypothesis 2B: The hypothesis that there will be higher number of the 5As utilized with intervention participants as compared to control participants will be tested with a general linear model (e.g., ANCOVA) to examine the effect of condition on the number of weight-related topics utilized. Visual inspection will be utilized to examine differences between conditions on each of the 5As due to the small sample size and to not inflate error.